Attachment 17

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Docket No. FDA-2019-N-3065

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

from $107 million per year to $122 million per year, with a mean estimate of $114 million per year, using a seven percent discount rate (2018$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

Table 1. Summary of the Informational Effects and Costs of the Final Rule (in millions of 2018$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Informational Effects		Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and help reduce disparities in knowledge about the negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized $millions/year	$114.4	$106.6	$122.2	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		$106.7	$100.0	$113.5	2018	3%	20 Years	

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a seven percent discount rate, discounted relative to year 2016, the estimated annualized net costs equal $73 million in 2016 dollars over an infinite horizon. Based on these costs, this final rule is considered a regulatory action under EO 13771.

tribes, unlike states, do not receive payments for smoking cessation programs from the Master Settlement Agreement.

(Response 13) We disagree that the tribal consultation for the proposed rule was inadequate. There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers. Tribal manufacturers are implicitly included in any analysis of domestic manufacturers. We did not receive comments providing us with new information regarding increased costs that we could incorporate into the analysis.

4. Comments on Break-even Approach

(Comment 14) One comment requested that FDA should "reach an explicit conclusion as to whether the proposed rule's informational benefits are likely to outweigh costs." Other comments suggested comparing the magnitude of the break-even analysis with estimates, such as value of a statistical life, number of people impacted by the rule, and WTP for pictorial health warnings estimated in the literature.

(Response 14) As described in the text below, despite the informational effects of the rule, there is a high level of uncertainty around quantified economic benefits at this time and we therefore apply a break-even analysis. We believe that comparing the break-even calculation with the suggested study results may be misleading.

(Comment 15) Multiple comments suggested conducting break-even analysis per smoker, not per pack.

(Response 15) FDA disagrees with these comments. A focus on smokers alone would be unduly narrow, as it would exclude any benefits to nonsmokers, who will also be exposed to the required warnings on cigarette packages and in cigarette advertisements.

(Comment 16) Multiple comments suggested alternative break-even calculations that would estimate the number of statistical lives that would need to be "saved" through reduced smoking-related deaths to break even.

(Response 16) FDA disagrees with these comments. In addition to being the leading cause of preventable death in the United States, smoking "leads to disease and disability and harms nearly